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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472
29156	7590	01/11/2006	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			HAWES, PILI ASABI	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Summary***

Receipt of Applicant's Remarks filed 10-31-2005 is acknowledged. Claims 1-12 and 19-22 and 26-29 are pending in this action. As set forth in the previous office action, Claims 1-12 and 19-22 and 26-29 are rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 19-22 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amend the claims to delete the phrase "less than the enteral administration amount" to recite "less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect". This amendment is not sufficient to overcome the rejection as set forth in the previous office action or as set forth by the Board of Patent Appeals and Interference Decisions on Appeal mailed 09-10-2004.

The rejection is not overcome for the following reasons:

The Board as set forth on pages 4 and 5, describe various amounts of aspirin formulations. One of ordinary skill in the art would be aware that aspirin is used for the treatment of headaches as well as for preventing heart attacks, and the amount of

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aspirin for the treatment of these ailments vary. It is unclear what amount of aspirin fall within the "less than typical amount" since one cannot determine the exact typical amounts of aspirin to treat headaches or heart conditions since this amount depends on age, weight, gender, and other factors that are patient and population dependent. Thus the metes and bounds of what a typical amount is, is not defined in a manner sufficient to make one of ordinary skill understand what amounts constitute a typical amount, thus the "less than typical amount" can also not be determined.

Likewise, the Board as set forth on page 6, discuss the specification example given as support for their being sufficient explanation of a "typical amount" using the chewing gum formulation with 50 mg of caffeine in comparison with the 100 mg oral tablet dosage. The Board set forth that "even assuming, therefore, that the 'typical amount' of caffeine administered is 100 mg, the specification provides no basis on which to extrapolate that dosage to other agents or medicaments." This argument is still applicable over the instant claims, even though applicants have added the phrase "that is swallowed by the individual to achieve a bioequivalent effect" because there is no basis for determining from the specification what the typical amount would be for all the various types of medicaments. Examiner notes that claim 1 recited a method of delivering a medicament. This is a generic term that encompasses all known medicaments. One of ordinary skill in the art would recognize that a typical dosage is determined based on many factors such as gender, age, weight, and medical conditions. Thus a typical amount for one patient population might be different than a typical amount from another patient population with differing sets of factors and

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illnesses. Thus it is not within the level of one of ordinary skill to be able to determine what the various typical dosage amounts would be for all the medicaments known to man, as that amount would needs be determined based on the needs of the patient population being treated.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes  
Examiner-1615

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600